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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,481	02/10/2004	Scott A. Waldman	08321-0168 US1	1053

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EXAMINER
JOYCE, CATHERINE

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,481	WALDMAN ET AL.	
	Examiner	Art Unit	
	Catherine M. Joyce	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-65 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-35, 42-51, as drawn to a method of treating an individual who has metastasized colorectal cancer cells by increasing the number of ST receptor molecules on the surface of a metastasized colorectal cancer in an individual, classified in class 424, subclass 184.1.

II. Claims 36-41, as drawn to a pharmaceutical composition comprising a sterile, pyrogen free ST receptor ligand, classified in class 530, subclass 300.

III. Claims 1-35, 52-58, as drawn to a method of imaging a metastasized colorectal tumor in an individual by increasing the number of ST receptor molecules on the surface of a metastasized colorectal cancer in an individual, classified in class 424, subclass 9.1.

IV. Claims 1-35, 59-60, as drawn to a method of determining whether an individual has metastasized colorectal cancer, classified in class 424, subclass 9.1.

V. Claims 1-35 and 61-63, as drawn to a method of delivering an active compound to a colorectal cell in an individual, classified in class 424, subclass 184.1.

VI. Claim 64 and 65, as drawn to a method of inducing a cytostatic effect in, or inhibiting the proliferation of, a primary or metastasized colorectal, gastric, or esophageal cancer, classified in class 424, subclass 184.1.

3. The inventions are distinct, each from the other, because of the following reasons:

The inventions of groups I, III-VI are distinct methods that employ different method steps and reagents in different patient populations. For example, the methods of group I are drawn to methods of treating an individual with metastasized colorectal cancer by increasing the number of ST receptors, the methods of group III are drawn to methods of imaging a metastasized colorectal cancer by increasing the number of ST receptors, the methods of group IV are drawn to methods of determining whether an individual has metastasized colorectal cancer by increasing the number of ST receptors, the methods of group V are drawn to methods of delivering an active compound to a colorectal cell, and the methods of group VI are drawn to methods of treating cancer by administering ST receptor binding ligands. While the searches for the different methods would be overlapping they would not be coextensive. Thus, searching any of groups I, III-VI together would pose an undue search burden. The inventions of group II is related to the inventions of groups I and III-VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process such as affinity chromatography. While the searches for the product of group II and the methods of groups I and III-V would be overlapping, they would not be coextensive. Thus, searching any of groups I-V together would pose an undue search burden.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Further, the following election of species are required.

If applicant elects group I, III, IV or V election of a specific ST receptor ligand from the following list is required: an anti-ST receptor antibody; an ST receptor binding peptide. This is not an election of species, and is instead a restriction requirement.

If an ST receptor binding peptides is elected above, Applicant is further required to elect one of the following ST receptor binding peptides: the peptide of SEQ ID NO:2, the peptide of SEQ ID NO:3, the peptide of any one of SEQ ID NOs:5-56.

If applicant elects group I, III, IV or V election of a specific mode of administration for the ST receptor ligand from the following list is required: into the circulatory system, intravenously, intratumorally.

If applicant elects group III or IV election of specific ST receptor binding moiety from the following list is required: the peptide of SEQ ID NO:2, the peptide of SEQ ID NO:3, the peptide of any one of SEQ ID NOs:5-56.

If applicant elects group III or IV election of a specific agent from the following list is required: a radioactive agent, a radiostable agent.

If a radioactive agent above is elected, election of a specific radioactive agent from the following list is required: ^{43}K, ^{52}Fe, ^{57}Co, ^{67}Cu, ^{67}Ga, ^{68}Ga, ^{77}Br, ^{81}Rb, ^{81}MKr, ^{87}MSr, ^{99}MTc, ^{111}In, ^{113}MIn, ^{123}I, ^{125}I, ^{127}CS, 129Cs, ^{131}I, ^{132}I, ^{197}Hg, ^{203}Pb, ^{206}Bi, ^{47}Sc, ^{67}Cu, ^{90}Y, ^{109}Pd, ^{123}I, ^{125}I, ^{131}I, ^{186}Re, ^{188}Re, ^{199}Au, ^{211}At, ^{212}Pb, ^{212}B, ^{32}P and ^{33}P, ^{71}Ge, ^{77}As, ^{103}Pb, ^{105}Rh, ^{111}Ag, ^{119}Sb, ^{121}Sn, ^{131}Cs, ^{143}Pr, ^{161}Tb, ^{177}Lu, ^{191}Os, ^{193}MPt and ^{197}Hg.

If a radiostable agent above is elected, for group III, election of a specific agent from the following list is required: compounds that cause cell death; compounds that inhibit cell division; compounds that induce cell differentiation.

If a radiostable agent above is elected, for group III, election of a specific therapeutic agent from the following list is required: chemotherapeutics, toxins, and radiosensitizing agents.

If a chemotherapeutic, toxin or radiosensitizing agent above is elected, election of a specific corresponding agent, if any such corresponding agent, from the following list is required: methotrexate, doxorubicin, daunorubicin, cytosinarabinoside, etoposide, 5-4 fluorouracil, melphalan, chlorambucil, cis-platin, vindesine, mitomycin, bleomycin, purothionin, macromomycin, 1,4-benzoquinone derivatives, trenimon, ricin, ricin A chain, Pseudomónas exotoxin, diphtheria toxin, Clostridium perfringens phospholipase C, bovine pancreatic ribonuclease, pokeweed antiviral protein, abrin, abrin A chain, cobra venom factor, gelonin, saporin, modeccin, viscumin, volkensin, nitroimidazole, metronidazole and misonidazole

If applicant elects group VI, election of a specific disease from the following list is required: primary colorectal cancer, primary gastric cancer, primary esophageal cancer, metastasized colorectal cancer, metastasized gastric cancer, metastasized esophageal cancer.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 of the other invention.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were

made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine M. Joyce
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER